

Competing Studies Policy

The CTG may need to determine the relative priority of two or more studies competing for the same target population. The Management Committees of these studies and the CTG Executive should aim to determine priority by discussion and mutual agreement. If agreement cannot be reached, the CTG Executive has ultimate authority to determine relative priority. The following principles will guide discussion and, if required, be used by the CTG Executive to make determinations of relative priority are as follows:

1. Completion of CTG studies funded by major funding bodies, such as the NHMRC, must be given the highest priority.
2. For a study to be endorsed, the management committee must agree to comply with this CTG policy on competing studies.
3. A study that has been endorsed will have priority over a study that has not yet been endorsed. Priority is conferred by the order in which potentially competing studies were endorsed and is not influenced by the order in which studies are first presented for discussion. Prior endorsement of a pilot or phase II study does not automatically mandate priority or endorsement of a subsequent larger study, but this factor should be given due weight.
4. A study seeking endorsement must demonstrate feasibility as a component of the endorsement process.
 - The Management Committee that proposes a new study has a responsibility to be aware of existing endorsed studies with which their study may compete.
 - The Chair of the CTG and reviewers also have a responsibility to anticipate competition between studies.
 - Where competition may occur, demonstration of feasibility must include consideration of the effects of recruitment by the proposed study on existing endorsed studies. This applies whether an existing endorsed study has commenced recruitment or not.
 - Demonstration of feasibility may require provisional agreement to participate from a sufficient number of non-competing sites to ensure that the study is viable. Alternatively, it may require a demonstration that entry criteria are sufficiently different to those of existing endorsed studies to ensure viability.
 - Endorsement may be made contingent on obtaining successful funding. This is intended to avoid the problem of an endorsed but unfunded study preventing alternative studies from obtaining endorsement and seeking funding.
 - Endorsement may be made contingent on a commitment that recruitment does not commence until it would not significantly impact on an existing endorsed study.
 - Demonstration of feasibility may be greatly enhanced by providing agreement for co-enrollment of patients with other concurrent studies.
5. An existing endorsed study may fail to progress and become a barrier to endorsement of a new proposed study. Under these circumstances the CTG Executive should discuss the situation with the Management Committee of the endorsed study. The CTG Executive may then specify a period of time after which the new proposed study will be granted endorsement and may be granted priority.
6. The CTG may act to prevent two or more endorsed studies from competing for funding at the same time.